

510(k) Summary

Prepared on July 8, 2008

1. General Information

JUL 17 2008

Trade Names of Device: Visensia®
Visensia® with Alert
Visensia® Alert

Common/Usual Name: Accessory to multi-parameter patient monitor (bedside or ambulatory)

Classification Name: Physiological Patient Monitor (with arrhythmia detection or alarms)

Submitters Name and Address: OBS Medical
11495 N Pennsylvania St., Ste 250
Carmel, IN 46032
Tel 317-581-3937
Fax 317-581-8941

Manufacturer: OBS Medical
11495 N Pennsylvania St., Ste 250
Carmel, IN 46032
Tel 317-819-3937
Fax 317-581-8941

2. Device Description

Visensia® is a software accessory to standard multiple parameter physiological patient monitors (bedside or ambulatory) or clinical information systems. It operates on a standard PC, or personal computer.

Visensia® is a software device that through advanced signal processing can combine physiological signals in order to produce a single index (Visensia® index) representation of patient condition.

Visensia® is a computerized analysis system that can accept multiple channels of physiological data (for example heart rate, respiratory rate, temperature, blood pressure and oxygen saturation as inputs). Through advanced signal processing, Visensia® can identify changes in patient status.

3. Indications for Use

Visensia® with alert is an accessory to multi-parameter patient monitors (bedside, ambulatory, or centralized location) or clinical information systems and is indicated for use by health care professionals with those non-paediatric high dependency care patients for whom multi-parameter patient monitoring has been routine.

Visensia® provides the clinician with a patient status index (Visensia® Index) based on a weighted average of five or four vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The Visensia® Index is a single measure of a patient's condition and represents how different the patient's vital signs are with respect to normality. Visensia® with Alert is an adjunct to and is not intended to replace vital sign monitoring and as such does not contain alarms, but alerts the physician to changes in the patient's physiological status.

When a Visensia® Alert has activated, it means that the Visensia® Index has reached and/or surpassed the default threshold and indicates that attention should be brought to the patient.

4. Substantial Equivalence

Visensia® is substantially equivalent to the following devices:

Predicate device: A-2000 EEG Monitor with BIS

Company: Aspect Medical Systems

510(K) Number: K030267

A-2000 EEG Monitor with BIS is an EEG monitoring system that monitors the state of the brain of an anesthetized or sedated patient. Raw EEG information obtained from patient sensors is processed with the complex Bispectral Index (BIS) algorithm and a number between 1 and 100 calculated and displayed to the clinician. This BIS index and associated trend graph provides a direct indication of the patient's level of anaesthesia and includes an alerts or alarm feature.

Visensia® is substantially equivalent to the A-2000 EEG Monitor with BIS in that it also takes a patient's physiological signals and processes them in order to provide the clinician with an index and associated trend graph indicative of the patient's state.

Predicate device: Propaq 200 Series multi-parameter physiological monitor

Company: Welch Allyn Protocol, Inc

510(K) Number: K012451

Visensia® is a software accessory to multi-parameter physiological patient monitors and as such is substantially equivalent to the Propaq 200. Visensia® and Propaq 200 provide real time monitoring and display of heart rate, respiration rate, blood pressure, temperature and oxygen saturation. Visensia® additionally provides a real time trend display of the data fusion of these vital signs.

Predicate device: Sonicaid System 8002

Company: Oxford Instruments Medical

510(K) Number: K992607

Sonicaid System 8002 is a software accessory for the computerized analysis of antepartum cardiotocograms (CTGs). It informs the clinician whether a CTG meets a number of criteria that are indicative of a normal CTG. These criteria were established by examination of historical clinical data.

Visensia® is substantially equivalent to Sonicaid System 8002 in that its displayed graphical representation of the fused vital signs is created by computer analysis and provides decision support to a clinician in the determination of normality based on a model derived from historic clinical data.

Predicate device: Equivital™

Company: Hidalgo

510(K) Number: K061993

The Equivital™ device combines physiological parameters into one index, "Physiological Welfare Index" and provides indications and alerts if physiology exceeds predefined boundaries. Visensia® combines physiological parameters into one index, the Visensia® Index (VSI), and

5. Performance Studies

Design verification: Design verification testing of Visensia® hardware and software against the specified requirements has been conducted and Visensia® has been found to meet the specifications.

Design validation: Design validation testing of Visensia® index model has been conducted and concluded that device specifications conformed with user needs and intended use.

Electrical Safety: Visensia® is composed of standard, off the shelf PC computer components. There is no contact with the patient and the user assumes no risk greater than that when using a standard desk-top personal computer.

Clinical Testing: Clinical data illustrates the effectiveness of Visensia® and the usefulness of the alert function. The data correlates patient deterioration with alerting function.

6. Conclusion

Based on the indications for use and performance studies, Visensia® is substantially equivalent to currently marketed devices for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

OBS Medical
c/o Mr. Wayne Nethercutt
Vice President, Clinical and Regulatory Affairs
11495 N. Pennsylvania St. Ste., 250
Carmel, IN 46032

Re: K081140

Trade Name: Visensia ® with Alert
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II
Product Code: MHX
Dated: July 8, 2008
Received: July 10, 2008

Dear Mr. Nethercutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, ~~please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474.~~ For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K081140

Device Name: Visensia® with Alert

Indications For Use:

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use X AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081140

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